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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/625,646

07/23/2003

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03/14/2008

EXAMINER

GROSS, CHRISTOPHER M

ART UNIT

PAPER NUMBER

1639

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/625,646	<b>Applicant(s)</b> QIAO ET AL.	
	<b>Examiner</b> CHRISTOPHER M. GROSS	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 17-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16,28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Responsive to communications entered 12/12/2007. Claims 1-28 are pending. Claims 17-27 are withdrawn. Claims 1-16, 28 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Priority***

1. This application has a filing date of 7/23/2003. Applicant makes no claim for the benefit of any prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c).

#### ***Withdrawn Objection(s) and/or Rejection(s)***

2. The rejection of claims 2-5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn in view of applicant's amendments to the claims.

#### ***Maintained Claim Rejection(s) - 35 USC § 102***

3. Claims 1,2,6,9 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by **Bauer et al** (US Patent 5639589 – IDS entry 1/21/2005).

#### ***Response to Arguments***

Applicant argues not all elements are taught.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

Protein Microarray (Support)

First, applicant argues see p 7 (12/12/2007), Bauer et al do not teach a protein microarray.

In response to applicant's argument that Bauer et al does not teach a protein microarray but rather a photographic film, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, the only structural limitation concerning protein microarrays appears in part (a) of claim 1, drawn to a protein microarray support.

In so far as said structural limitation of claim 1(a) is concerned, it is noted according to p 5 line 10 of the present specification (paragraph 0027 of the published application), plastic is a commonly used support for protein microarrays. Bauer et al teach both polyester and polyethylene (i.e. plastic) supported films, both of which represent a type of plastic.

The examiner submits that the photographic film of Bauer et al meets the structural limitations of claim 1 and absent evidence to the contrary is capable of performing as a protein microarray.

#### Transparent Adhesive Interlayer

Second applicant argues, see paragraph bridging p 7-8 (12/12/2007), that Bauer et al do not teach an adhesive interlayer that does not interfere with protein microarray applications.

In this regard, according to paragraph 0033 of the present published application, interlayers which are optically transparent and do not fluoresce include constituents such as gelatin and poly alkyl methacrylates. In this vein, Bauer et al teach in example 1 a gelatin/poly(n-butyl acrylate-co-2-amino-ethyl methacrylate hydrochloride-co-2-hydroxyethyl methacrylate, called P-1, as one potential interlayer. The examiner submits that P-1 of Bauer et al provides an interlayer that does not optically interfere with protein microarray applications, as defined by the present application.

#### Gelatin Layer Specificity

Third applicant argues, see paragraph pp 8-9 (12/12/2007), that Bauer et al do not teach a gelatin layer which is (a) substantially resistant to non-specific binding and (b) containing functional groups capable of specific binding of biological probes. In this regard, applicant asserts that non-specific binding is a known problem in working with gelatin, as evidenced by the present specification on p 18 line 16 p 9 line 2 of the present application (published application paragraph 0074) and US Patent 6,797,393 (referred to as '393) column 9, example 5.

(a) The examiner respectfully disagrees. To circumvent the problem of non-specific binding in protein microarray applications, paragraph 0074 of the present published application indicates that protein microarrays are typically immersed in a *blocking agent* solution including, for instance, bovine serum albumin (BSA) or polyethylene glycol (PEG) or polylysine.

In this vein, solely to rebut applicant's argument, evidence provided by Sawyer et al (US Patent 5,602,041) in table 1 indicates, in fact, gelatin *is* a blocking agent

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recognized in the prior art. In column 2, line 30-33 Sawyer et al describe the characteristics of an ideal blocker (i.e. blocking agent) as including the ability to inhibit non-specific binding. The examiner therefore submits that gelatin is a blocking agent effective against non-specific binding, a fact well recognized in the prior art.

In conclusion, the function of blocking agents is to inhibit non-specific binding, thus a blocking agent such as the gelatin of Bauer et al inherently possesses the characteristic of being substantially resistant to non-specific binding, as set forth in claim 1(b) in accordance with evidence provided by Sawyer et al.

Further evidence concerning gelatin as a blocking agent is provided in the passage of '393 which applicant cites; example 5, Table 3 indicates gelatin as providing effective blocking of non-specific binding, as compared to aminopropylsilane (APS) or polyethyleneimine (PEI) treated glass.

(b) In so far as gelatin inherently containing functional groups capable of specific binding of biological probes is concerned, as mentioned in the Office Actions mailed 4/5/2006 and 1/5/2007, evidence provide by Schor et al (1996 J. Cell Sci. 109:2581-2590) indicates fibronectin is a protein which binds denatured collagen (a.k.a. gelatin). In particular, on page 2583, right column, first paragraph last line Schor use gelatin-agarose chromatography to affinity purify fibronectin expressed in insect cells. Thus, according to Schor et al gelatin acts as a *specific* binder for fibronectin.

Additionally, solely to rebut applicant's argument, additional evidence provided by Mosher (US Patent 5,460,955) indicates, more generally, fibronectin fusion proteins may be purified using a gelatin based affinity column. In particular, Mosher states in

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column 2, lines 37-38 that a fibronectin fusion proteins bind strongly and substantially uniquely to a gelatin-containing chromatography column. The capability of gelatin containing chromatography columns, such as disclosed by Schor et al and Mosher, to selectively adsorb fibronectin containing proteins provides compelling evidence that gelatin inherently bears functional groups capable of specific (i.e. substantially unique) binding of biological probes, such as the fibronectin fusion proteins of Mosher et al.

Moreover, the examiner submits, assuming arguendo, that gelatin does not provide for specific adsorption of fibronectin and is prone to non-specific binding, as applicant alleges, the methodology of Mosher and Schor et al would fail because other proteins would bind to the gelatin column. In other words non-specific binding would not afford the specificity required for effective affinity chromatography.

Applicant is welcome to present evidence on the record with regard to gelatin chromatography as being unsatisfactory with regard to affinity purification of fibronectin fusion proteins based upon non-specific adsorption onto a gelatin column.

***Maintained Claim Rejection(s) - 35 USC § 103***

4. Claims 1,2,6,9,15 and 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bauer et al** (US Patent 5639589 – IDS entry 1/21/2005) in view of **Roberts et al** (US Patent 5380642).

Claims 1,2,6,9,15 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bauer et al** (US Patent 5639589 – IDS entry 1/21/2005) in view of

**Arenkov et al** (2000 Analytical Biochemistry 278:123-131– IDS entry 11/10/2003 transferred to PTO-892).

Claim 1,2,6,9,15 and 10-12 rejected under 35 U.S.C. 103(a) as being unpatentable over **Bauer et al** (US Patent 5639589 – IDS entry 1/21/2005) in view of **Dorogushin et al** (Soviet Union Patent SU308662 – IDS entry 1/21/2005 transferred to PTO-892 4/5/2006)

Claims 1,2,6,9,15 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bauer et al** (US Patent 5639589 – IDS entry 1/21/2005) in view of **Bonderman** (US Patent 5348852).

#### *Response to Arguments*

Applicant argues: (i) not all elements are taught; (ii) the references lack a likelihood of success; (iii) the present invention represents surprising results.

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

(i) Applicant does not offer further arguments regarding the above obviousness rejections beyond what was set forth with regard to the 35 U.S.C. § 102 rejection regarding missing elements. To the extent that Applicant is merely repeating their previous argument, the Examiner contends that those issues were adequately addressed in the above section (3.), which is incorporated in its entirety herein by reference.

(ii-iii) Applicant argues, see p 10-11 (12/12/2007), that the combined teachings of Bauer et al with any of Roberts et al, Arenkov et al, Dorogushin et al or Bonderman lack



an expectation of success because gelatin is a known non-specific binder, and not a very good non-specific binder at that, and concludes that one of ordinary skill in the art would therefore be dissuaded from using gelatin as a highly specific binding material, therefore the instant invention constitutes surprising results.

Applicant cites p 18 line 16 to p 9 line 2 of the present application (published application paragraph 0074) and US Patent 6,797,393 to Qiao (i.e. '393 mentioned above) et al column 9, example 5 as support for this assertion.

#### Gelatin as a Blocking Agent

The examiner respectfully disagrees. In so far as p 18 line 16 to p 9 line 2 of the present application (published application paragraph 0074), this passage mentions, "Typically, the protein microarray will be **immersed in** a solution containing a **blocking agent** to block the non-specific binding sites..." Emphasis added. Solely to rebut applicant's argument, evidence provided by Sawyer et al (US Patent 5,602,041) indicates in table 1 that gelatin itself *is* a blocking agent. Blocking agents, by necessity, must inhibit non specific binding, as indicated by Sawyer in column 2, lines 29-31. Therefore, the examiner submits the gelatin in the photographic element of Bauer, identical to the claimed protein microarray element, save intended use, is inherently substantially resistant to non-specific binding.

In so far as Qiao et al ('393) column 9, example 5 is concerned, the examiner respectfully submits that applicant has not considered example 5 in context with the rest of the document. In particular, in column 5, lines 32-35 of Qiao et al states "As shown in this invention, gelatin also renders a surface that substantially reduce[s] background

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noise that is a result of non-specific binding." Example 5, the examiner submits, illustrates this concept: column 10, lines 24-28 state "The results show that the gelatin surface has significantly lower non-specific binding capacity than the other amine functional group containing materials. Note, for example, that the gelatin coated surface adsorbs significantly less BSA than the amine coated surfaces."

The examiner submits that based on a complete reading of Qiao with additional evidence provided by Sawyer et al that gelatin represents a blocking agent known in the art at the time the invention was made. Gelatin has the inherent capability of low non-specific binding capacity, as would be expected from a blocking agent. In this vein, applicant admits on p 11 (12/12/2007) gelatin is not a very good non-specific binding material, again which would be expected from a blocking agent.

#### Specific Binding of Gelatin by Fibronectin

In so far as specific binding is concerned, the results are not surprising given evidence provided by Schor et al (1996 J. Cell Sci. 109:2581-2590) which indicates fibronectin is a protein which binds denatured collagen (a.k.a. gelatin) in a specific manner. In particular, on page 2583, right column, first paragraph last line Schor use gelatin-agarose chromatography to affinity purify fibronectin expressed in insect cells. Thus, according to Schor et al gelatin acts as a *specific* binder for fibronectin.

Furthermore, solely to rebut applicant's argument, additional evidence provided by Mosher (US Patent 5,460,955) indicates, more generally, fibronectin fusion proteins may be purified using a gelatin based affinity column. In particular, Mosher states in column 2, lines 37-38 that a fibronectin fusion proteins bind strongly and substantially

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uniquely to a gelatin-containing chromatography column. The capability of gelatin containing chromatography columns, such as disclosed by Schor et al and Mosher, to selectively adsorb fibronectin containing proteins provides compelling evidence that gelatin inherently bears functional groups capable of specific (i.e. substantially unique) binding of biological probes, such as the fibronectin fusion proteins of Mosher et al.

5. Claims 1,2,6,9,15 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bauer et al** (US Patent 5639589 – IDS entry 1/21/2005) in view of **Christopher** (US Patent 2309340).

Applicant argues: (i) not all elements are taught; (ii) the references lack a likelihood of success; (iii) the present invention represents surprising results; (iv) the references are non-analogous art

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

(i) Applicant does not offer further arguments regarding the above obviousness rejections beyond what was set forth with regard to the 35 U.S.C. § 102 rejection regarding missing elements. To the extent that Applicant is merely repeating their previous argument, the Examiner contends that those issues were adequately addressed in the above section (3.), which is incorporated in its entirety herein by reference.

(ii-iii) Applicant does not offer further arguments regarding the above obviousness rejections beyond what was set forth with regard to the 35 U.S.C. § 103

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rejection over Bauer et al in view of Roberts et al, etc. regarding a likelihood of success and the present invention representing surprising results. To the extent that Applicant is merely repeating their previous argument, the Examiner contends that those issues were adequately addressed in the above sections, which are incorporated in its entirety herein by reference.

(iv) Applicant argues, see p 15-16 first paragraph (12/12/2007) that applicant's field of endeavor relates to protein microarrays and neither of Bauer et al or Christopher et al disclose any information regarding protein microarrays. Applicant contends "The instant invention is a protein microarray that utilizes an interlayer to bind substrate and gelatin layer. The gelatin layer is substantially resistant to non-specific binding and contains functional groups capable of binding biological probes. Neither reference, applicant contends relates to this field. Furthermore, neither reference discloses the problem solved by the instant invention" Emphasis added.

In so far as Bauer et al and Christopher et al not being related to the problem at hand, it is noted, according to paragraph 0001 of the present published application, the present invention concerns using gelatin to allegedly improve specific attachment of biomolecules. The examiner submits the problem at hand concerned employing gelatin in both the top binding layer (i.e. as set forth in claim 1(b) as well as an interlayer comprising gelatin, as set forth in dependent claims 9 and 13

The examiner submits that each of instant invention, Bauer et al and Christopher employ gelatin for various intended uses and thus each of Bauer et al and Christopher

are reasonably pertinent to the particular problem with which the applicant was concerned.

In so far as the gelatin of the present invention being substantially resistant to non-specific binding and containing functional groups capable of binding biological probes, the examiner submits that resistance to non-specific binding and containing functional groups capable of binding biological probe are both inherent properties of gelatin, as evidenced by Sawyer et al, Schor et al and Mosher et al and detailed in the above sections entitled "Gelatin as a Blocking Agent" and "Specific Binding of Gelatin by Fibronectin"

6. Claims 16 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bauer et al** (US Patent 5639589 – IDS entry 1/21/2005) **in view of Arenkov et al** (2000 Analytical Biochemistry 278:123-131– IDS entry 11/10/2003 transferred to PTO-892) as applied to claims 1,2,6,9,15 and 3-5 above, and further in view of **Cone et al** (US Patent 2235202).

Applicant argues: (i) not all elements are taught; (ii) the references lack a likelihood of success; (iii) the present invention represents surprising results; (iv) the references are non-analogous art

Applicant's arguments have been fully considered but they are not deemed persuasive for the following reasons.

(i) Applicant does not offer further arguments regarding the above obviousness rejections beyond what was set forth with regard to the 35 U.S.C. § 102 rejection

regarding missing elements. To the extent that Applicant is merely repeating their previous argument, the Examiner contends that those issues were adequately addressed in the above section (3.), which are incorporated in its entirety herein by reference.

(ii-iii) Applicant does not offer further arguments regarding the above obviousness rejections beyond what was set forth with regard to the 35 U.S.C. § 103 rejection over Bauer et al in view of Roberts et al, etc. regarding a likelihood of success and the present invention representing surprising results. To the extent that Applicant is merely repeating their previous argument, the Examiner contends that those issues were adequately addressed in the above section (4.), which is incorporated in its entirety herein by reference.

(iv) First applicant argues, see p 21 first full paragraph line 10 (12/12/2007) that applicant's field of endeavor relates to protein microarrays and none of Bauer et al, Arenkov et al or Cone et al disclose any information regarding protein microarrays, however applicant's attention is respectfully invited to the title and figure 1 of Arenkov et al which concern protein microchips. The examiner submits the protein microarrays are synonymous with protein microchips.

Second applicant argues, see p 21 second full paragraph lines 4-5 (12/12/2007), "The instant invention... utilizes an interlayer to bind a substrate and gelatin layer...The references do not relate to this field." The examiner submits that problem in the art the interlayer addresses, paraphrasing paragraph 0009-0010 and 0033 of the present published application, addresses the need in the art for a strong adhesive interlayer,

between the gelatin layer and support layer, to prevent frilling when wet or stripping when dry which is also optically transparent. Suitable materials include gelatin, acrylamide polymers and poly alkyl methacrylates.

In this regard, it is noted that each of Bauer et al, Arenkov et al and Cone concern strong transparent adhesives. Arenkov et al advocate polyacrylamide; Cone advocates gelatin based glues; Bauer et al suggest the gelatin/polymethacrylate mixture called P-1, mentioned above in section (3.) above. The examiner submits that the strong transparent adhesives of Arenkov et al, Bauer et al and Cone are reasonably pertinent to the particular problem with which the applicant was concerned, that of a strong transparent adhesive and therefore Bauer et al, Arenkov et al and Cone each represent analogous art.

Third applicant argues, see p 21 second full paragraph lines 6-7 (12/12/2007), the gelatin of the present invention is substantially resistant to non-specific binding and containing functional groups capable of binding biological probes, the examiner submits that resistance to non-specific binding and containing functional groups capable of binding biological probe are both inherent properties of gelatin, as evidenced by Sawyer et al, Schor et al and Mosher et al and detailed in the above sections entitled "Gelatin as a Blocking Agent" and "Specific Binding of Gelatin by Fibronectin" Both Bauer et al and Cone concern gelatin. Arenkov et al concerns biological probes.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross  
Examiner  
Art Unit 1639

cg

/Mark L. Shibuya, Ph.D./

Primary Examiner, Art Unit 1639